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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/585,645	06/01/2000	Huda Y. Zoghbi	P01899US2	4965

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EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1633

DATE MAILED: 01/15/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/585,645

Applicant(s)

ZOGHBI ET AL.

Examiner

Celine Qian

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 40-50 and 113-123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 40-50 and 113-123 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election with traverse of Group IV and addition of claims 120-124 in paper 8 is acknowledged. Claims 40-50 and 112-124 are pending in the application. Upon further review of the claims, it was found that the examiner inadvertently overlooked the requirement to separate nucleic acid and amino acid sequence into different groups in the earlier office action. Therefore, further restriction is required. The office apologizes for the inconvenience that is caused by this mistake.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 46, 47, 50, 116, 117, 118, 119 and 121, drawn to a method of generating hair cell by delivering an atonal-associated nucleic acid sequence, and a composition comprising atonal-associated nucleic acid sequence, classified in class 514, subclass 44.
- II. Claims 49 and 120, drawn to a method of generating hair cell by delivering an atonal-associated amino acid sequence, and a fusion protein comprising an atonal-associated amino acid sequence and a desired amino acid sequence, classified in class 530, subclass 350.
- III. Claim 122, drawn to a method of generating hair cell by delivering an atonal-associated nucleic acid sequence and a second nucleic acid sequence encoding a non-atonal-associated therapeutic agent, classified in class 514, subclass 350.

Art Unit: 1633

Claims 40-45, 48, 112-115 and 123 are generic to Groups I and II, and will be examined in so far as it reads on the elected subject matter.

The inventions are distinct, each from the other for the following reasons.

Inventions I and II are patentably distinct because they are drawn to materially different compositions and methods that require different starting material and modes of operation. The nucleic acid in Group I is chemically, biologically and functionally distinct from the amino acid in Group II. In addition, a method of generating hair cell using nucleic acid involves different steps than using amino acid. Thus, the inventions of Group I are patentably distinct from the inventions of Group II.

Inventions I, II are patentably distinct from III because they are drawn to methods that require different starting material and modes of operation. The methods of Groups I and II involves different steps than the method of Group III. Thus, the inventions of Groups I and II are patentably distinct from the inventions of Group III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). This application contains claims directed to the following patentably distinct species of the claimed invention: 1) human atonal-associated nucleic acid and amino acid sequence

Art Unit: 1633

(Hath1); 2) mouse atonal-associated nucleic acid and polypeptide sequence (Math1). The nucleotide sequences and polypeptide sequences of groups I and II are subject to a restriction requirement. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Amino acid sequences of different polypeptides are also structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Accordingly, only one (1) independent and distinct nucleotide/polypeptide sequence will be examined in a single application without restriction. For example, if group I is elected, applicant must select one sequence from among claim 118 (Hath1) or 119 (Math1).

Applicant is advised that reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J Clark can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.


Application/Control Number: 09/585,645

Page 5

Art Unit: 1633

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.  
January 3, 2002

  
REMY YUCEL, PH.D  
PRIMARY EXAMINER